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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/546,139	07/19/2006	Michel Chateau	34076/US/2	1181
25763 7590 03/31/2008 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498				
EXAMINER				
LONG, SCOTT				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/546,139

Applicant(s)

CHATEAU ET AL.

Examiner

Scott D. Long

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 1 February 2008.

Claim Status

Claims 13-14 are pending. Claim 13 is amended. Claims 1-12 and 15-37 are cancelled. Claims 13-14 are under current examination.

Priority

This application claims benefit as a 371 of PCT/FR04/00354 (filed 02/17/2004).

The instant application has been granted the benefit date, 17 February 2004, from the application PCT/FR04/00354.

RESPONSE TO ARGUMENTS

Claim Rejections - 35 USC § 102

The rejection of claims 13-14 under 35 USC 102(b) as anticipated over Schnappinger et al (Arch. Microbiol. 1996; 165: 359-369) is withdrawn in response to Applicant's amendment or arguments.

The applicant has submitted amendments to claim 13 that overcome the rejection. Therefore, the examiner hereby withdraws the rejection of claims 13-14 under 35 USC 102(b).

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamori et al. (Applied Microbial Biotechnology, 1999; 52: 179-185).

Claim 13 is directed to a method for the producing an evolved protein comprising
a) preparing a modified microorganism by genetic modification of cells of an initial microorganism, wherein the production or consumption of a metabolite is inhibited when the initial microorganism is grown on a defined medium, wherein the ability of the modified microorganism to grow is impaired; b) culturing the modified microorganism obtained in step (a) on the defined medium causing the modified microorganism to evolve compensatory metabolic pathways, where the defined medium can contain a co-substrate promoting the evolution; c) selecting the evolved microorganism of step (b) able to grow on the defined medium, if necessary with a co-substrate; wherein the evolved microorganism produces an evolved protein.

The specification defines an evolved protein as “a sequence of amino acids (protein sequence) that differs in at least one amino acid from the initial protein sequence after selection” (page 4, lines 5-8). According to the specification, selection is defined as “a culture method used to select microorganisms that have evolved in such a way

that a modification does not affect growth anymore" (page 3, lines 22-24). The specification does not define the phrase "compensatory metabolic pathway."

Nakamori et al. teach preparation of evolved microorganisms permitting a modification of metabolic pathways (abstract). Nakamori et al. teach preparing a modified microorganism by genetic modification of cells of an initial microorganism so as to inhibit the production or consumption of a metabolite (methionine) when that microorganism is grown on a defined medium, see page 180 wherein E.coli JM 109 cells in the late exponential phase in LB medium were mutagenized. Nakamori et al. produced L-methionine-analogue resistant mutants (page 180). Nakamori et al. teach culturing the modified microorganism thereby obtained on said defined medium to cause it to evolve, where the defined medium can contain a co-substrate to allow such evolution and c) selecting a modified microorganism able to grow on , said defined medium, if necessary with a co-substrate, see page 180 under selection and cultivation of L-methionine-producing mutants (i.e. an evolved microorganism). Nakamori et al teach biosynthesis pathway of amino acids and methionine (see title and abstract). Nakamori et al. teach "To determine the production of L-methionine, all of the halo-forming colonies were culture in M1 medium at 30°C for 72 h. It was found that four mutants...produced around 300 mg L-methionine/liter, while no L-methionine was detected in the parent strain." (page 181, Results). It is clear that the evolved protein is produced by the evolved microorganism.

Claim 14 is directed to the method as claimed in claim 13, characterized in that the produced evolved protein is purified. Nakamori et al. teach, "The enzymes in the

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soluble fraction obtained from sonicated cells were assayed without further purification.” (page 182). While Nakamori et al. indicate a crude extract of enzyme was assayed, the instant application and claims do not indicate the degree of purification required, so the examiner interprets the teaching of Nakamori et al. as satisfying the limitations of claim 14, since the enzyme is no longer in a viable cell.

Accordingly, Nakamori et al. anticipated the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 12-13 of copending Application No. 10/781499. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the method steps of producing an evolved protein (claim 13 of instant application) require producing an evolved microorganism (as recited in claim 1 of 10/781499). The evolved microorganism of 10/781499 would produce an evolved protein. Furthermore, claims 12-13 of 10/781499 recite production and isolation of an evolved protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long Patent Examiner, Art Unit 1633	/Janet L. Epps-Ford/ Primary Examiner, Art Unit 1633
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